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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,082	07/15/2003	Josephus Wilhelmus, A., M. van Oers	294-166	7102

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EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,082	VAN OERS ET AL.	
	Examiner	Art Unit	
	A R Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Claims 1-16 are pending.

Submitted Information Disclosure Statement (I.D.S) is noted.

Response to Amendment

The receipt of preliminary amendment of 7/15/2003 is acknowledged. Claims 1-16 are pending before the examiner.

Claim Rejections - 35 USC § 112

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "reduce" this is a relative terminology, and is subject to varied interpretation. In addition, the claim is vague and indefinite since the intended metes and bounds of "substrate and a proteolytic enzyme" is/are not defined. This affects the dependent claims.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the enzyme, the substrate, the control, the intended sample, etc....

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: when to add the enzyme, when to add the substrate, how much to add, when to detect, etc... None of the conditions needed to perform the method is given and since the specification lacks teaching the claim is indefinite.

Claim 4 is confusing, vague and indefinite for recitation of "test sample may be affected by an internal and/or external factor", what are the internal or external factors? Is the weather an intended factor? The intended factors are not defined.

Claim 6 is vague and indefinite; the intended antibody is not defined. The claim has been interpreted in light of the specification and since the specification does not teach the antibody that binds to prion protein the claim is vague and indefinite. This affects claim 7.

Claim 8 is vague and indefinite for recitation of "or a functionally equivalent protease", the intended protease(s) is/are not defined.

Claim 16 provides for the use of method according to claim 1 to monitor protease activity, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification as filed is deficient in providing adequate teaching to practice the claimed invention. At the onset Applicants are reminded that this field is highly unpredictable, as Applicants' own disclosure is testament to the unpredictability of the field. The specification sets out a theoretical explanation for determination of false positive out-come in prion test, without any clear teaching. The disclosure sets out by describing the problems that currently exists in determination of presence of normal prion proteins verses the miss-folded prion protein, and how and why a new method of testing would be useful, however, none of the problems are solved nor taught so one of ordinary skill in the art may practice the invention absent undue experimentation. The required experimentations that are needed to enable the claimed invention are not considered routine. The specification does provide any working examples, and one of ordinary skill in the art cannot follow the theoretical recitation of the disclosure to enable the claimed invention, absent undue experimentation. The Office has not been able to locate any teaching that would embrace the model presented by the Applicants in either pre or post filing literature. Still further, the specification does not provide any antibody to be utilized in the method, and yet the claims are

directed to utilizing antibodies to detect prions and distinguish the false positive, again absent clear teaching undue experimentation would be required. The disclosure does not provide any control for monitoring the claimed system; there is nothing in the method that accounts for the presence of protease inhibitory factors that may be present in a "biological sample", the specification does not even address some fundamental problems that one of skill in the art would face trying to practice this invention. The disclosure speaks of establishing a prion testing in plasma or whole blood referred to as biological sample, and alludes to the fact that state of the art does not recognize the presence of prion in the blood. Yet the claimed invention is directed to any and all samples including detection of prions in whole blood or plasma. This is not adequate disclosure, Applicants cannot expect others enable their claimed invention, while they obtain patent protection.

Therefore, Applicants have general statements regarding the method of detecting false positive for prions, however with regard to an unpredictable field, this does not constitute an adequate disclosure, as stated above. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a method for determination of false positive prion samples. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate

teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Subject Matter Allowable over Prior art

Claims 1-16 are free of prior art, given failure of the prior art to teach or reasonably suggest the claimed method.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

6/22/2004